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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,591	09/03/2008	Jenneke Adriana Cadee	0470-062554	8519

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,591	CADEE ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2/2006, 5/27/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed on 5-24-2010. Claims 54-57 are amended. Claims 58-67 are new. Claims 54-67 are pending and under examination.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

3. The drawings filed on date 8/4/2006 in this application have been accepted. No further action by Applicant is required.

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

5. The information disclosure statement filed 11/22/2006 and 5/27/2009 has been considered. Initialed copies are enclosed.

Election/Restrictions

6. Applicant's election with traverse of claims 54-57 is acknowledged. The traversal is on the ground(s) that claims 1-53 would not represent an undue burden because each group requires: a) solution of lactoferrin of acid pH; and/or b) a solution of lactoferin and a metal chelating agent. This is not found persuasive because the search for each Group as is not co-extensive particularly with regard to literature search. Furthermore a reference which would anticipate the invention of one group, would not necessarily anticipate or make obvious of another group because a burden in examining distinct inventions acquire different issues and further require independent searches.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 54-57 and 59-67 are rejected under 35 U.S.C. 102(b) as being anticipated by (Naidu et al WO/2000/72874A1).

The claims are drawn to a method for wound care, comprising administering the composition a solution comprising lactoferrin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 54), a method for oral care, comprising administering the composition as claimed in claim 40 a solution comprising lactoferfin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 55); a method for decontamination of inert surfaces comprising administering the composition in a solution comprising lactoferrin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 56); a method for decontamination of food products, comprising administering the composition a solution comprising lactoferrin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 57); a method, wherein the food products to be treated comprise meat (claim 59), wherein the solution contains 0.1 to 10 mM of EDTA (claims 60-63), wherein the solution contains 0.2 to 20% (w/v) of lactoferrin (claims 64-67).

Naidu et al teach a method of preventing or inhibiting the growth of a microbe in or on a human subject, comprising: administering to a human subject a pharmaceutically acceptable composition by a pharmaceutically acceptable delivery route (see pg. 8 lines 20-35), wherein said composition is a pharmaceutically acceptable composition of matter comprising an aqueous buffer solution containing EDTA as a metal chelating agent and a physiologically acceptable salt and containing a mixture of native lactoferrin wherein said aqueous buffer solution having a pH between about 5.5 and about 7.5 (see claim 17, pg. 14 lines 24-30, and abstract). Naidu et al teach a non-systemic delivery route is useful for infections of the skin or externally accessible

wounds (see pg. 24 liens 10-20). Naidu et al teach methods for reducing or inhibiting microbial contamination of a composition subject to microbial contamination, for example, a foodstuff, such as a meat product (e. g., a beef, pork or poultry product) (see pg. 28 lines 1-30). Naidu et al teach a method to treat product and thereby reduce or inhibit microbial contamination thereof (see claim 17 and pg. 28-30), which correlates to a method for decontamination of food products. Naidu et al teach a method for inhibiting microbial growth in a foodstuff and inventive foodstuffs by employing the antimicrobial properties of lactoferrin, are useful alternative means of preventing food contamination and further teach said method intended for bacteriostatic food packaging or handling such as food containers comprising a material suitable for contact with food such as gloves or mitts utensils and for application for surfaces such as countertops, desks, chairs, etc. (see pg. 28-30 and pg. 31 lines 9-37), which correlates to a method for decontamination of inert surfaces. Naidu et al teach oral hygiene applications include the prevention or treatment of oral infections, plaque (e. g., caused by Streptococcus mutans), and periodontal diseases (e. g., caused by *Porphyromonas gingivalis, Prevotella intermedia, or Actinobacillus* (see pg. 15 lines 1-10). Naidu et al teach a delivery through the oral mucosa that can comprise an inner layer containing the therapeutic agent of choice, whereby the inner layer can have one surface adapted to contact and adhere to the moist mucosal tissue of the oral cavity and may have an opposing surface adhering to an overlying non-adhesive inert layer, wherein the inner layer can have one surface adapted to contact and adhere to the moist mucosal tissue of the oral cavity and may have an opposing surface adhering to an overlying non-adhesive inert layer (see pg. 15). Naidu et al teach mixtures of lactoferrin in an aqueous dispersion embodiment, from about 0.001% wt/vol to about 2.5% wt/vol, preferably from about 0.5% wt/vol to about 2.0% wt/vol, most preferably about 1% wt/vol of LF, which correlates to a method, wherein the solution contains 0.2 to 20% (w/v) of lactoferrin (see pg. 13 lines 25-35). Naidu et al teach the composition contains a buffer system including a combination of a physiologically acceptable acid, such as ethylenediamine tetraacetic acid (EDTA), (which can be added in aqueous form or by gassing an aqueous solution or emulsion with carbon dioxide) (see pg. 14 lines 13-25), wherein the molar ranges of acid: base: salt is about (acid): 0.1 to 0.01M (base) which correlates to a method, wherein the solution contains 0.1 to 10 mM of EDTA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 54-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Naidu et al WO/2000/72874A1).

The claims are drawn to a method for wound care, comprising administering the composition a solution comprising lactoferrin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 54), a method for oral care, comprising administering the composition as claimed in claim 40 a solution comprising lactoferrin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 55); a method for decontamination of inert surfaces comprising administering the composition in a solution comprising lactoferrin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 56); a method for decontamination of food products, comprising administering the composition a solution comprising lactoferrin, the solution: a) having a pH below 3; or b) containing a metal chelating agent, and having a pH below 5 (claim 57), wherein the inert surfaces comprise surgical instruments (claim 58); a method, wherein the food products to be treated comprise meat (claim 59), wherein the solution contains 0.1 to 10 mM of EDTA (claims 60-63), wherein the solution contains 0.2 to 20% (w/v) of lactoferrin (claims 64-67).

Naidu et al teach a method of preventing or inhibiting the growth of a microbe in or on a human subject, comprising: administering to a human subject a pharmaceutically acceptable

composition by a pharmaceutically acceptable delivery route (see pg. 8 lines 20-35), wherein said composition is a pharmaceutically acceptable composition of matter comprising an aqueous buffer solution containing EDTA as a metal chelating agent and a physiologically acceptable salt and containing a mixture of native lactoferrin wherein said aqueous buffer solution having a pH between about 5.5 and about 7.5 (see claim 17, pg. 14 lines 24-30, and abstract). Naidu et al teach a non-systemic delivery route is useful for infections of the skin or externally accessible wounds (see pg. 24 liens 10-20). Naidu et al teach methods for reducing or inhibiting microbial contamination of a composition subject to microbial contamination, for example, a foodstuff, such as a meat product (e. g., a beef, pork or poultry product) (see pg. 28 lines 1-30). Naidu et al teach a method to treat product and thereby reduce or inhibit microbial contamination thereof (see claim 17 and pg. 28-30), which correlates to a method for decontamination of food products. Naidu et al teach a method for inhibiting microbial growth in a foodstuff and inventive foodstuffs by employing the antimicrobial properties of lactoferrin, are useful alternative means of preventing food contamination and further teach said method intended for bacteriostatic food packaging or handling such as food containers comprising a material suitable for contact with food such as gloves or mitts utensils and for application for surfaces such as countertops, desks, chairs, etc. (see pg. 28-30 and pg. 31 lines 9-37), which correlates to a method for decontamination of inert surfaces. Naidu et al teach oral hygiene applications include the prevention or treatment of oral infections, plaque (e. g., caused by Streptococcus mutans), and periodontal diseases (e. g., caused by *Porphyromonas gingivalis, Prevotella intermedia, or Actinobacillus* (see pg. 15 lines 1-10). Naidu et al teach a delivery through the oral mucosa that can comprise an inner layer containing the therapeutic agent of choice, whereby the inner layer can have one surface adapted to contact and adhere to the moist mucosal tissue of the oral cavity and may have an opposing surface adhering to an overlying non-adhesive inert layer, wherein the inner layer can have one surface adapted to contact and adhere to the moist mucosal tissue of the oral cavity and may have an opposing surface adhering to an overlying non-adhesive inert layer (see pg. 15). Naidu et al teach mixtures of lactoferrin in an aqueous dispersion embodiment, from about 0.001% wt/vol to about 2.5% wt/vol, preferably from about 0.5% wt/vol to about 2.0% wt/vol, most preferably about 1% wt/vol of LF, which correlates to a method, wherein the solution contains 0.2 to 20% (w/v) of lactoferrin (see pg. 13 lines 25-35). Naidu et al teach the

composition contains a buffer system including a combination of a physiologically acceptable acid, such as ethylenediamine tetraacetic acid (EDTA), (which can be added in aqueous form or by gassing an aqueous solution or emulsion with carbon dioxide) (see pg. 14 lines 13-25), wherein the molar ranges of acid: base: salt is about (acid): 0.1 to 0.01M (base) which correlates to a method, wherein the solution contains 0.1 to 10 mM of EDTA.

Naidu et al does not teach a method, wherein the inert surfaces comprise surgical instruments.

Naidu et al teach a method of preventing or inhibiting the growth of a microbe using said compositions in cleaners, soaps, etc. on surfaces such as bed stands in hospital settings for the prevention of nosocomial infection, which correlates to a method, wherein the inert surfaces.

Naidu et al is silent with regard to surgical instruments.

It would have been obvious to one of skill in the art to modify the method, wherein the inert surfaces (as disclosed by Naidu et al) to incorporate the method to comprise surgical instruments because Naidu et al teach a method of preventing or inhibiting the growth of a microbe using said compositions in cleaners, soaps, etc. on surfaces such as bed stands in hospital settings for the prevention of nosocomial infection.

One would have a reasonable expectation of success because a methods using a composition comprising lactoferrin and a metal chelating agent (as disclosed by Naidu et al) is well known in the art.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie

Examiner

Art Unit 1645

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645